DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 1, 2014

Nanjing Jusha Display Technology Co., Ltd.
℅ Ms. Li Le
Certification Manager
8A, Block 1, Nanjing International Service
Outsourcing Mansion, No. 301
Hanzhongmen Street, Nanjing 210036
CHINA

Re: K141679
Trade/Device Name: Jusha-C61 LCD Monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: June 24, 2014
Received: June 30, 2014

Dear Ms. Le:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141679

Device Name

JUSHA-C61 LCD Monitor

Indications for Use *(Describe)*

JUSHA-C61 LCD Monitor is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It does not support the display of mammography images for diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Office of Chief Information Officer
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	May 6, 2014
Submitter:	Nanjing Jusha Display Technology Co., Ltd Add: 301, 8F Block A, No.1, Nanjing International Service Outsourcing Mansion, Hanzhongmen Street, Nanjing, 210036 China
Contact Person:	Li le Certification Manager Nanjing Jusha Display Technology Co., Ltd Tel: +86-25- 83305050 Fax: +86-25- 58783271
Device Trade Name:	JUSHA-C61 LCD Monitor
Common/Usual Name:	6MP Color LCD Monitor
Classification Name: Product Code:	Display, Diagnostic Radiology 21CFR 892.2050 PGY
Predicate Device(s):	EIZO RX650;K134002
Device Description:	JUSHA-C61 LCD Monitor is the display system with the high resolution (3280*2048), high luminance (700cd/m^2), 10 bit display colors expanded to 12 bit color expansion technology, 7 DICOM look up table and one GAMMA2.2 look up table inside. In particular, JUSHA-C61 LCD Monitor contains CGA function, it is specially made by JUSHA, it can automatic identify gray and color signals, then gray area calls DICOM LUT and color area calls GAMMA2.2 LUT. JUSHA-C61 LCD Monitor has ambient brightness adapting and presence induction system, with these this display can automatic adjustment according to different requirements in order to achieve the best results. The product is consisted of the following components: - 30.0 inch, a-Si TFT Liquid Crystal Display - JUSHA-C61 motherboard/FR-4/REV:2.0 - JUSHA-C61 LCD Monitor software - Power Adapter - Data Cable. The LCD Monitor is designed, tested, and will be manufactured in accordance with both mandatory and voluntary standards: IEC 60601-1Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance 2005+CORR.1(2006)+CORR.2(2007) IEC 60601-1-2 Edition 3:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance –

	Collateral standard: Electromagnetic compatibility - Requirements and tests.
Intended Use:	JUSHA-C61 LCD Monitor is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It does not support the display of mammography images for diagnosis.
Technology:	JUSHA-C61 LCD Monitor is the display system with the high resolution (3280*2048) with electronic capabilities for evaluation of high resolution medical images, high luminance (700cd/m^2), 10 bit display colors expanded to 12 bit color expansion technology, 7 DICOM look up table and one GAMMA2.2 look up table inside. In particular, JUSHA-C61 LCD Monitor contains CGA function, it is specially made by JUSHA, it can automatic identify gray and color signals, then gray area calls DICOM LUT and color area calls GAMMA2.2 LUT. JUSHA-C61 LCD Monitor has ambient brightness adapting and presence induction system, with these this display can automatic adjustment according to different requirements in order to achieve the best results.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The LCD Monitor complies with voluntary standards as following: IEC 60601-1Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance 2005+CORR.1(2006)+CORR.2(2007) IEC 60601-1-2 Edition 3:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. JUSHA-C61 is substantially equivalent to EIZO RX650. JUSHA-C61 employs the maximum resolution values same as that of EIZO RX650. Comparison table of the principal characteristics of 2 devices is shown in the Attachment 1. The following quality assurance measures were applied to the development of the system: Risk Analysis Requirements Reviews Design Reviews Raw materials verification Testing on unit level (Module verification) Integration testing (System verification) Final acceptance testing (Validation) Performance testing (Verification) Safety testing (Verification)

	Summary of Clinical Tests: The subject of this premarket submission, LCD Monitor, did not require clinical studies to support substantial equivalence. The proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device. Therefore, the subject device is determined as safe and effectiveness.
Conclusion:	Nanjing Jusha Display Technology Co., Ltd Considers the JUSHA-C61 LCD Monitor to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

Attachment 1:

Attributes	Predicate Device	Proposed Device
Product	EIZO RX650	JUSHA-C61 LCD Monitor
510(k) Number	K134002	K141679
Screen technology	30.0" Color TFT LCD Panel	30.0" Color TFT LCD Panel
Viewing angle（H，V）	Horizontal 176°,Vertical 176°	Horizontal 170°,Vertical 170°
Resolution	2048 x 3280/3280x 2048	2048 x 3280/3280x 2048
Display area	645.5(H) x 403.0 (V) mm	645.5 (H) x403.0 (V) mm
Contrast Ratio	1000:1	1000:1
Recommended Luminance	400cd/m^2	400cd/m^2
Pixel Pitch	0.197x0.197 mm	0.197x0.197 mm
Backlight	LED	LED
Display Colors	10-bit ,1.07 billion colors	12-bit , 68.7billion colors
Luminance calibration	Built in calibration sensor provided	Built in calibration sensor provided
Input signals	DVI standard 1.0, DisplayPort 1.1a	DVI standard 1.0, DisplayPort 1.1a
Input terminational	DVI-D Dual Link x2 Display Port x2	DVI-D Dual Link x2 Display Port x2
Display controller	Off the shelf	Off the shelf
Power Requirement	AC 100~240V 50~60Hz	AC 100~240V 50~60Hz

Power Consumption/Save Mode	108W/less than 6W	100W/less than 1.5W
Power Management	DVI DMPM DisplayPort 1.1a	DVI DMPM DisplayPort 1.1a
USB Ports/standard	1 upstream (endpoint), 2 downstream/ Rev. 2.0	1 upstream (endpoint), 2 downstream/ Rev. 2.0
Dimensions w/o stand (W x H x D)	Without stand: 692mmx466mmx109 mm With stand: 692mmx478~643mmx302 mm	Without stand: 704mm x 478mm x 81mm With stand: 704mm x 611mm x292mm
Applicable standard	1 IEC 60601-1Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance 2005+CORR.1(2006)+CORR.2(2007) 2 IEC 60601-1-2 Edition 3:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.	1 IEC 60601-1Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance 2005+CORR.1(2006)+CORR.2(2007) 2 IEC 60601-1-2 Edition 3:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.